



WHAT IS KOSELUGO® SELUMETINIB?

- A targeted therapy used to treat some types of neurofibroma.
- Prescribed and renewed by your paediatrician, dermatologist, neurologist or oncologist.
- Available from community pharmacies on presentation of your prescription.



Opaque capsule available in two dosages:

- White capsule, dosed at **10 mg**, with “SEL 10” in black ink
- Blue capsule, dosed at **25 mg**, with “SEL 25” in black ink



- Do not store above 30°C. Store in the original bottle in order to protect from moisture and light (do not remove the dessicant sachet).

Keep the bottle tightly closed. Keep out of the sight and reach of children.





- Do not take the capsules out of the vial to put them in a pillbox.

- Wash your hands carefully before and after handling the capsules.



- Do not throw away opened vials, please return them to your pharmacist.

HOW TO TAKE THIS MEDICINE

When?:..... and:.....	= 2 doses per day** (ideally 12 hours apart), at set times, with or without a meal
How?		Swallow the capsules whole, with water, at the same time every day. Do not open, chew or dissolve them. 

You can use your **medical diary*** and a **calendar** to note doses:

Do not stop taking or change how you take your treatment without consulting your doctor.

This leaflet is not a prescription, please refer to your most recent prescription

**Your doctor may prescribe a single daily dose.

IF YOU FORGET TO TAKE YOUR MEDICINE OR VOMIT



- **If it has been less than 6 hours since your dose was due:** take the missed dose. Take your next dose at the usual time. **If it has been more than 6 hours since your dose was due:** do not take the missed dose. Take your next dose at the usual time, do not take a double dose. Keep a record in your medical diary*.
- **If you throw up,** do not take another dose. Take your next dose at the usual time, do not take a double dose. Keep a record in your medical diary*.

INTERACTION WITH OTHER MEDICINES AND OTHER INTERACTIONS

Check with **your doctor or pharmacist** that the medicines (prescribed or over-the-counter), other substances (foods, spices and plants, including **grapefruit**, **St. John's Wort** and **liquorice**, probiotics, essential oils, food supplements, etc.) and derivative products you use are **compatible with your treatment**. The molecules they contain, their dose and how often they are taken can interact with your treatment and affect its effectiveness and the occurrence of side effects.









- You and your partner must use effective methods of contraception (condoms and another method) throughout treatment **and for 7 days after the last dose**.
- Selumetinib may reduce the effectiveness of oral contraceptives.
- Stop breastfeeding during treatment if applicable.




*Patient diary available (in French) at www.omedit-fiches-cancer.fr

WHAT SIDE EFFECTS CAN OCCUR WITH KOSELUGO® SELUMETINIB?

Like all medicines, selumetinib may cause side effects, although not everybody gets them.

Side effects	Prevention
 Dry skin	Only shower/bath once per day (max. 15 minutes at 32°C). Use soap-free gel or a dermatological bar. Pat dry. Use moisturiser (cream or milk). Wear loose, light cotton clothing. Use detergent suitable for sensitive skin (no laundry softener). Drink 1.5 to 2 L water per day.
 Digestive effects: diarrhoea, nausea, vomiting	Monitor your weight and remember to hydrate (1.5 to 2 L water per day). In case of diarrhoea , eat foods low in fibre (carbohydrates, carrots, bananas etc.). Avoid foods that can stimulate digestion (dairy products, raw fruit/vegetables, grains, fatty foods, spices). In case of nausea/vomiting , divide your meals into several small meals and eat slowly. Avoid fatty, fried or spicy foods, and foods that smell strongly. Avoid having an empty stomach (can worsen nausea). Drink between, rather than with, meals. Use your prescribed antiemetics if applicable.
 Inflamed mouth	Use a soft toothbrush and menthol-free, additive-free toothpaste. Keep your lips hydrated (ask your pharmacist for advice, particularly if you are receiving oxygen therapy. Stimulate saliva production (ice cubes, sorbets). Prefer liquids and blended foods. Avoid alcohol, tobacco, coffee and acidic, salty, irritating, spicy and crunchy foods. Use pain medication. Use your prescribed mouthwash (not mouthwash containing alcohol).
 Low red blood cells	Contact your doctor in case of paleness, shortness of breath on exertion or when resting, persistent tiredness, palpitations, dizziness or headaches.
 Visual disorders	Consult your doctor promptly if you experience decreased or blurred vision.
 High blood pressure	Headaches, dizziness, and tinnitus are the first warning signs of high blood pressure. Measure your blood pressure (resting and sitting down, in the morning before breakfast and in the evening before going to bed; take three measurements two minutes apart); keep a record of your results. Exercise regularly (suitable activities) (30 minutes 3 times per week). Limit salt (max. 5 g per day) and alcohol. Eat a diet low in saturated fats (animal fats) and high in fibre.
 Tiredness	Eat a balanced diet. Avoid using psychostimulants (e.g. coffee, tobacco, alcohol). Take care when driving. Rest during the day, while maintaining up to moderate levels of activity. Go to bed at a regular time and get sufficient sleep at night.
 Swelling of the face or limbs (oedema)	Eat a diet low in salt. Avoid tight clothing. If your legs swell, raise your feet when sitting. Wear compression stockings; put them on when getting up in the morning. Weigh yourself regularly. Consult your doctor if this type of swelling occurs.

 Only the most common side effects are listed here. For more information, read the Patient Leaflet included with your medicine or ask your doctor or pharmacist.
You can also ask your [Regional Pharmacovigilance Centre](#) and report any side effects online: [signalement-sante-gouv-fr](#)



Remember to go for the lab tests prescribed by your doctor.

WHAT TO DO IF YOU EXPERIENCE SIDE EFFECTS

- Take the medicine prescribed to counteract the side effects, as prescribed.
- Follow the preventive measures.

Contact your doctor rapidly in case of:

- Blurred vision, loss of vision, black spots in your vision (floaters)
- Shortness of breath, swollen legs, ankles or feet
- Fever, difficulty breathing
- Worsening tiredness, nausea, vomiting
- Any persistent or worsening side effect



Useful contacts:

Note:
